Synairgen plc

('Synairgen' or the 'Company')

Results for the year ended 31 December 2021

Southampton, UK – 25 May 2022: Synairgen plc (LSE: SNG), the respiratory company developing SNG001, an investigational formulation for inhalation containing the broad-spectrum antiviral protein interferon beta, today announces its preliminary statement of audited results for the year ended 31 December 2021.

Highlights (including post period-end)

Operational

- Recruited 623 patients into the Company's Phase 3 SPRINTER trial, a double-blind, placebo-controlled trial conducted in 17 countries, to investigate the efficacy and safety of SNG001 in people hospitalised with COVID-19.
    - The trial did not meet the primary endpoints, as previously announced. There was, however, an encouraging signal in reduction in the relative risk (RRR) of progression to severe disease or death within 35 days (26% reduction in the Intention-to-Treat (ITT) population and 36% reduction in the Per Protocol population).
    - Further follow-on analyses indicated stronger treatment effects in high-risk patient sub-groups, with the strongest effect observed in patients with compromised respiratory function despite being on supplemental oxygen (44% reduction in the ITT population and 70% reduction in the Per Protocol population), who comprised approximately one-third of the overall trial population.
    - The data has further validated the favourable safety profile of SNG001.
- Recruitment started and completed in the US Government's Phase 2 ACTIV-2 trial conducted in the US to investigate SNG001 in people with COVID-19 at home, prior to hospitalisation.
    - The Data Safety Monitoring Board graduated SNG001 from Phase 2 to Phase 3 in the ACTIV-2 trial, sponsored by the National Institute of Allergy and Infectious Diseases (NIAID), part of the National Institutes of Health, and led by the NIAID-funded AIDS Clinical Trials Group (ACTG). The NIAID subsequently decided to cease the Phase 3 ACTIV-2 study.

- *In vitro* studies confirmed potency against multiple variants of the SARS-CoV-2 virus including Alpha, Beta and Gamma, followed early in 2022 by Delta and Omicron.
- Significant development and scale-up of manufacturing capability.
- Strengthened its Board of Directors and senior leadership team.

Financial

- Loss from operations for the year ended 31 December 2021 of £57.9 million (2020: £17.7 million), with R&D expenditure increasing from £15.5 million to £52.9 million (2020: £15.5 million) on account of Phase 3 trial and manufacturing activities.
- The research and development tax credit increased from £3.8 million to £9.2 million, resulting in a loss after tax of £48.7 million (2020: £13.9 million loss).
- Cash balances of £33.8 million at 31 December 2021 (31 December 2020: £75.0 million).

Richard Marsden, CEO of Synairgen, said: "Since the completion and reporting of the Phase 3 SPRINTER data and subsequent analyses of different high-risk patient groups within the trial, we remain encouraged that SNG001 has the potential to show clinically important benefits in preventing disease progression and death in patients with severe viral lung infections.

"We are now working in haste on discussions with platform trial organisers and investigators, as well as regulatory authorities, the pharmaceutical and biotech industry and government bodies to identify and establish the optimal method of conducting further trials to confirm these findings and move forward, not just for COVID-19, but also as a potential treatment for patients hospitalised due to a range of viruses including influenza, RSV, adenovirus, para-influenza and rhinoviruses."

Results webcast details

A webcast will be hosted by Synairgen's management team at 12:00 BST today, followed by a Q&A for analysts.

The webcast link can be accessed here: Synairgen Preliminary Results webcast

To access details for the analyst Q&A, please contact: cscsynairgen@consilium-comms.com

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Notes for Editors

About Synairgen

Synairgen is a UK-based respiratory company focused on drug discovery, development and commercialisation. The Company's primary focus is developing SNG001 (inhaled interferon beta) for the treatment of severe viral lung infections, including COVID-19, as potentially the first host-targeted, broad-spectrum antiviral treatment delivered directly into the lungs. SNG001 has been granted Fast Track status from the US Food and Drug Administration (FDA). Founded by University of Southampton Professors Sir Stephen Holgate, Donna Davies and Ratko Djukanovic in 2003, Synairgen is quoted on AIM (LSE: SNG). For more information about Synairgen, please see www.synairgen.com.

CHAIRMAN'S STATEMENT

This year has marked significant progress for Synairgen and the development of our investigational candidate SNG001, inhaled interferon beta, for potential use in treating people with COVID-19. Built on a 15-year scientific foundation and strong rationale for use in COVID-19 and for other viruses that cause severe viral lung infections, the Synairgen team and our consultants, partners and advisers have been unwavering in their efforts to bring SNG001 to those patients who may benefit.

Our business has many challenges. We operate in an environment of political and market volatility against the ever-changing backdrop of COVID-19. Despite these challenges, we started and completed enrolment in SPRINTER, our first-ever Phase 3, double-blind, placebo-controlled clinical trial, conducted in 17 countries with more than 620 participants. It was obviously disappointing that the primary endpoints of the SPRINTER trial were not met, however we saw what we believe is an important signal in a key secondary endpoint towards a relative reduction in the risk of disease progression and death (36% in the Per Protocol population) compared with placebo, on top of current standard of care treatment. Subsequent *post hoc* analyses of subgroups recognised to be at higher risk of disease progression (such as the elderly, those with co-morbidities associated with worse COVID-19 outcomes, and those who showed signs of respiratory compromise despite use of oxygen) suggest further investigation is warranted. Full details are contained in the Operating Review. These findings *post hoc* indicate which patients are most likely to benefit from SNG001 and, coupled with its favourable safety profile, have enabled Synairgen to refine the strategy for the SNG001 development programme.

Outside the clinic, our *in vitro* studies of SNG001 have shown it to be potent against all SARS-CoV-2 variants tested to date, including Alpha, Beta, Gamma, Delta and Omicron.[1]

There have been substantial and rapid improvements in the standard of care in the treatment and prevention of severe illness caused by SARS-CoV-2 which means that the majority of patients are discharged from hospital without the need for higher levels of care such as high flow oxygen or ventilation. However, there remains a need to further improve standard of care for COVID-19 patients at high risk of progressing to more severe disease or death. In 2021, despite new therapies and successful vaccination programmes, deaths from COVID-19 still surpassed those of 2020.[2] As such, Synairgen is actively seeking inclusion of SNG001 in a platform trial or other trials for hospitalised patients so that the encouraging signal seen in reducing the relative risk of disease progression and death in SPRINTER can be confirmed.

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[1] Synairgen. SNG001 inhibits SARS-CoV-2 variant infection in cell based assays. 2021-2
[2] CBS News, November 23, 2021

During the year, the Board played an important role in working with the Company's management team to make strategic and operational decisions. In September, I was delighted to welcome Theodora Harold to the Board as a non-executive director and chair of the Audit Committee. I thank all of our Board Members for their sound judgement, challenge and advice throughout the year.

On behalf of the Board, I would like to thank our shareholders for their continued support, and Synairgen employees and partners for staying committed and focused through a year of challenge and change.

As we look ahead and continue to learn more about this virus which has affected the world so significantly, our priority, using carefully managed resources and in collaboration with experts, is clear: to rapidly confirm the important signal we've found from the SPRINTER trial in COVID-19 and to investigate SNG001 in patients hospitalised with a range of seasonal viruses such as influenza, Respiratory Syncytial Virus (RSV) and para-influenza.

SIMON SHAW

CHAIRMAN

OPERATING REVIEW

Introduction

There remains an urgent need for additional treatment options, with distinct mechanisms of action, for high-risk patients hospitalised due to COVID-19 and other viruses, particularly to prevent progression to severe disease or death. Vaccines, antibodies and antivirals have done much to reduce the risks associated with COVID-19, however there is growing evidence that protection from the virus afforded by vaccines is not comprehensive and may wane over time. Furthermore, there are limitations to many direct-acting COVID-19 therapeutics, particularly in respect of continuing efficacy against new variants as they emerge. Additional market research conducted by Synairgen also indicates that current therapies do not fully meet the current medical need.[3]

2021 achievements

2021 was a significant year in which Synairgen made important progress investigating SNG001 for the possible treatment of COVID-19 in both the hospital and home settings.

1. Started and completed recruitment into the Company's Phase 3 SPRINTER trial, a double-blind, placebo-controlled trial conducted in 17 countries to investigate the efficacy of SNG001 in 623 patients hospitalised with COVID-19.
2. Recruitment was started and completed in the US Government's ACTIV-2 Phase 2 trial conducted in the US to investigate SNG001 in people with COVID-19 at home, prior to hospitalisation.
3. *In vitro* studies confirmed potency against multiple variants of the SARS-CoV-2 virus including Alpha, Beta and Gamma (followed early in 2022 by Delta and Omicron).

In addition, the Company focused on the regulatory, commercial and manufacturing activities that would be required to support use of SNG001 in hospitals following potential regulatory approval including expedited routes.

Topline SPRINTER data

The topline data from the SPRINTER trial, announced in late February 2022, showed that the primary endpoints of earlier hospital discharge and recovery were not met, likely due to improvements in standard of care such as vaccination programmes, the use of antivirals and anti-inflammatories, and changes in hospital practices since the beginning of the pandemic. The Company did observe an encouraging signal with respect to a reduction in the relative risk of patients progressing to severe disease or death (36% in the Per

[3] IQVIA market research, December 2021. On file.

Protocol population[4]). Further *post h*oc analysis of this endpoint suggested that SNG001 prevented disease progression in patient groups with recognised risk factors, such as older age, the existence of certain co-morbidities and compromised respiratory function. The strongest effects were observed in patients with compromised respiratory function (high respiratory rate and low oxygen saturations) despite being on supplemental oxygen, who represented approximately one-third of the patients in the trial, where SNG001 significantly reduced the risk of progression compared to placebo (44% in the Intention-To-Treat population and 70% in the Per Protocol population) in this *post hoc* analysis.

Summary

Given the evolution of COVID-19, emergence of variants and the changing treatment landscape, and on the advice of our independent clinical and scientific advisers, we are actively seeking to have SNG001 included in further COVID-19 trials which would provide adequate statistical power to evaluate the encouraging effects we observed in SPRINTER, as well as further investigation of SNG001 in patients hospitalised with a range of seasonal viruses such as influenza, RSV and para-influenza.

Despite the challenging environment outlined above, Synairgen continues to explore the potential of SNG001 in three settings:

1. In people hospitalised with COVID-19, including in high-risk sub-populations such as those with compromised respiratory function, despite use of supplemental oxygen;
2. For possible use as a broad-spectrum antiviral for people hospitalised with other severe viral lung infections caused by a range of 'regular' seasonal viruses; and,
3. As a possible future pandemic preparedness option for government agencies.

Rationale for SNG001 in COVID-19

There is a strong scientific rationale underpinning SNG001 for use in treating COVID-19, combined with a good safety profile and a growing body of encouraging clinical data which will help us better understand the role SNG001 can play in helping patients at risk of developing severe illness due to respiratory viruses.

Interferon beta ('IFN-beta') is a naturally-occurring protein, orchestrating the body's antiviral responses. Synairgen's SNG001 is a formulation containing the fully glycosylated form of IFN-beta (IFN-beta-1a) for direct delivery to the lungs via specific nebulisers. It is near to pH neutral, and is free of mannitol, arginine

[4] The main reason patients were excluded from the Per Protocol population was failure to receive two full doses in the first three days of treatment.

and human serum albumin (which may be pharmacologically active in the airways), making SNG001 suitable for inhaled delivery direct to the site of infection.

There is strong evidence that deficiency in IFN-beta production by the lung could explain the enhanced susceptibility in higher-risk patient groups to developing severe lower respiratory tract (lung) disease during respiratory viral infections, including COVID-19.[5]

Viruses, including coronaviruses such as SARS-CoV-2, have evolved mechanisms to suppress IFN-beta production, helping the virus to evade the innate immune system. The addition of IFN-beta before or during viral infection of lung cells *in vitro* either prevents or greatly reduces viral replication.[6] The Company has conducted *in vitro* testing against SARS-CoV-2 variants of concern (VOC) including Alpha, Beta, Gamma, Delta and Omicron and shown potent antiviral activity at concentrations that are readily achievable following inhaled delivery of interferon beta.

Delivery via the inhaled route results in a high local concentration in the lungs, the site of the infection. We believe these concentrations could not be accomplished at the lining of the lungs via the injected route, and indeed recent studies have shown systemic use of IFN-beta through injection is ineffective in fighting COVID-19 in the lungs.[7]

2021 clinical progress in COVID-19

Synairgen conducted a Phase 2 trial of SNG001 in people with COVID-19 in 2020, consisting of both a Hospital and a Home Cohort. The Hospital Cohort generated positive results with patients treated with SNG001 being twice as likely to recover over the treatment period compared to those receiving placebo. This was a clear signal that patients on drug recovered faster than those on placebo. There were also trends towards prevention of progression to severe disease or death and faster hospital discharge. This was a robust, double-blind, placebo-controlled trial conducted at nine specialist hospital sites in the UK in the first few months of the pandemic, at a time when hospital practices for COVID-19 were not yet established, and when patients were unvaccinated and were not treated with antiviral and anti-inflammatory treatments available in 2021. The data from the Hospital Cohort were peer reviewed and published in the *Lancet Respiratory Medicine* in November 2020.

Building on the positive results seen in the Hospital Cohort of the Phase 2 trial, the Company worked with regulatory authorities to design a larger Phase 3 trial

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[5] Zheng Y, Zhuang MW, Han L, et al. Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) membrane (M) protein inhibits type I and III interferon production by targeting RIG-I/MDA-5 signaling. Signal Transduct Target Ther. 2020;5:299.

[6] Synairgen data on file.

[7] WHO Solidarity Trial Consortium. Repurposed Antiviral Drugs for Covid-19 — Interim WHO Solidarity Trial Results. N Engl J Med. 2021;384:497–511.

(SPRINTER) to evaluate SNG001 in people hospitalised due to COVID-19 who required supplemental oxygen.

Synairgen began recruitment into the SPRINTER trial in January 2021 and concluded recruitment in November 2021. The SPRINTER trial was a global Phase 3, randomised, placebo-controlled, double-blind, multi-site clinical trial assessing the efficacy and safety of inhaled SNG001 on top of standard of care for the treatment of adults hospitalised due to COVID-19 requiring treatment with supplemental oxygen by mask or nasal prongs. Patients requiring high-flow nasal oxygen therapy, non-invasive ventilation, or endotracheal intubation (invasive ventilation) and patients that were vaccinated at randomisation were excluded (exclusion of vaccinated patients was later removed via protocol amendment). COVID-19 was confirmed using a validated molecular test for the presence of the SARS-CoV-2 virus. The trial enrolled 623 patients, randomised (1:1) to treatment with inhaled SNG001 or placebo at more than 100 sites across the following 17 countries: Argentina, Belgium, Brazil, Colombia, France, Germany, India, Israel, Italy, Mexico, Netherlands, Portugal, Romania, Serbia, Spain, the United Kingdom and the United States.

There was no difference between SNG001 and placebo in the hospital discharge or recovery primary endpoints in the trial, with the majority of patients discharged from hospital within the treatment period. We believe this is due to the improvements in standard of care driven by vaccines, the use of antivirals and anti-inflammatories, and changes in hospital practices. For further context, when the Phase 2 trial was conducted in March 2020, systemic corticosteroids and antivirals for COVID-19 were not routinely being used. Accordingly, no patients in the Phase 2 trial received any of these treatments for COVID-19. When the Phase 3 SPRINTER trial was conducted in 2021, there was considerably higher routine use of dexamethasone and remdesivir, meaning that almost 90% of SPRINTER patients were also being treated with systemic corticosteroids, around 20% were taking remdesivir, and around 30% of patients were vaccinated to some degree.

Nevertheless, a 36% reduction in the risk of disease progression or death (a key secondary endpoint) was observed in the Per Protocol population, which trended towards statistical significance (p=0.119), which we believe is an important signal.

The potential importance of this signal triggered a more comprehensive, *post hoc* analysis of the SPRINTER data to 'stress test' the robustness of this encouraging observation. The analyses focused on the disease progression endpoint in high-risk groups and showed a consistent trend in favour of SNG001 with respect to a reduction in the risk of progression to develop severe disease or death. The strongest treatment effect was in patients who, despite being on supplemental oxygen, had compromised respiratory function at

baseline (low oxygen saturation or a high breathing rate). This group represented around one third of the overall trial population.

- Participants in the Per Protocol population with compromised respiratory function (oxygen saturation of ≤ 92% or respiratory rate ≥ 21 breaths/min at baseline) treated with SNG001 had a 70% reduction in the risk of progression to severe disease or death compared to placebo (Odds Ratio (95% Confidence Interval) 0.23 (0.06, 0.98); p=0.046).

SNG001 was well tolerated in the SPRINTER trial with a favourable safety profile consistent with previous studies:

- The proportion of patients with any treatment-emergent adverse events (TEAE) related to study treatment was 22.6% for SNG001 vs. 25.4% for placebo,
- The proportion of patients with any serious TEAE was 12.6% for SNG001 vs. 18.2% for placebo,
- The proportion of patients with a serious respiratory TEAE was 4.7% for SNG001 vs. 9.9% for placebo.

These findings are consistent with an effect on disease progression.

This trend seen with respect to prevention of progression to severe disease or death, supported by the *post hoc* analysis, provides a strong rationale to investigate SNG001 in a further targeted COVID-19 trial, and more widely in patients hospitalised with a range of seasonal viruses such as influenza, RSV and para-influenza, which can lead to severe viral lung infections requiring hospitalisation. The stronger treatment effect observed in patients with compromised lung function at baseline in the *post hoc* analyses suggests that these patients should be targeted in future trials.

Home use of SNG001 in the US Government's ACTIV-2 trial

SNG001 was also investigated during 2021 as part of the US National Institute of Health's ACTIV programme to accelerate the development of the most promising COVID-19 treatments with the ultimate aim of identifying treatments which reduce hospitalisations. The ACTIV-2 study, sponsored by the National Institute of Allergy and Infectious Diseases (NIAID), part of the National Institutes of Health, and led by the NIAID-funded AIDS Clinical Trials Group (ACTG), tested a number of treatments in adults in an outpatient setting who had documented positive SARS-CoV-2 infection.

The Phase 2 evaluation of SNG001 saw the recruitment of approximately 220 participants across US sites, in a home-based setting, split between SNG001 and placebo. If an investigational agent showed promise by demonstrating safety and efficacy signals through 28 days following administration, it moved from Phase 2 to Phase 3, which was planned to include significantly more patients.

In October 2021, the Data Safety Monitoring Board recommended graduation of SNG001, based on data from the Phase 2 trial, to Phase 3. As the Company and the ACTIV-2 team were preparing to initiate recruitment for Phase 3, the Omicron variant became the dominant variant in the US, causing a significant shift in the nature of the pandemic. In March 2022, due to the need to modify the study design in light of the emergence of the Omicron variant of SARS-CoV-2, the US National Institutes of Health (NIH) ACTIV-2 trial team asked Synairgen to temporarily pause preparation activities for ACTIV-2 Phase 3 until the timeline for the activation of SNG001 in the trial could be clarified. Several weeks later, the National Institutes of Health (NIH) halted all patient recruitment in ACTIV-2 and discontinued all arms of the trial, including the one to evaluate SNG001.

As a result, discussions with NIH, NIAIDS and the ACTIV teams are ongoing to try to identify an appropriate clinical trial to continue the evaluation of SNG001 in the home environment.

Adding to our finding from the Home Cohort of the Company's Phase 2 trial in 2020, the ACTIV-2 trial also demonstrated that patients can successfully initiate treatment "remotely", self-administering SNG001 at home with the support of a YouTube video. Importantly, patients can be initiated on SNG001 without the need for a face-to-face meeting with a healthcare professional, reducing the burden on hospital facilities and minimising the risk of onward infection.

We now anticipate receiving the Phase 2 data from the ACTIV-2 team in the summer of 2022, which will be factored into the SNG001 clinical development plan to further build the case that SNG001 may have an important role in combatting COVID-19 and future emerging virus threats.

Building Readiness for the Future

Over the course of 2021, in readiness for the possibility that our Phase 3 SPRINTER data would have been sufficient for regulatory submissions (which would require a high level of immediate activity to support use of SNG001 under expedited approval pathways), the Company began building its capabilities and capacity in the areas of regulatory, commercial, manufacturing, communications, quality and finance. This included strengthening its senior leadership team as well as establishing commercial and distribution partnerships and preparing the foundations for a US commercial organisation. With the SPRINTER data now analysed, the Company is carefully managing its team and cost base in order to progress the path for SNG001 as rapidly as possible using the various avenues as described.

Leadership team

The Company senior management team was strengthened with newly created roles including:

- Richard Hennings: Richard joined in March 2021 as Chief Commercial Officer, having previously held commercial leadership roles at Verona Pharma, Gilead Sciences, Novartis and AstraZeneca.
- Richard Francis: Richard joined in September 2021 as Senior Vice President for CMC, bringing more than 35 years' experience in the development, regulatory approval and commercialisation of many biopharmaceutical products including Cablivi®, Orthoclone OKT3®, Remicade®, and ReoPro®.
- Brooke Clarke: Brooke joined in September 2021 as Senior Vice President, Head of Communications, with more than 30 years' strategic communications and corporate affairs experience, including most recently leadership roles at Shire plc and Hikma plc.
- Gareth Walters: Gareth joined in October 2021 as Chief Regulatory Officer and brings a wide range of experience from pre-clinical to commercialisation. He previously held senior regulatory and commercial roles at Chugai Pharmaceuticals and Roche.
- Helen Gearing: Helen joined in December 2021 as Senior Vice President for Finance. Prior to joining Synairgen, Helen was responsible for leading, building and scaling the finance function of Seqirus, a global leader in influenza vaccines, and prior to that was with GSK.

Regulatory

In preparation for regulatory submissions in the US, Europe and the UK, Synairgen's regulatory team continued engagement with the US Food and Drug Administration (FDA), the EMA and the MHRA on requirements and content for regulatory submissions.

With SNG001 having been granted Fast Track status from the FDA, the US was the priority focus of preparatory activities for a potential regulatory Emergency Use Authorisation submission and launch.

With the SPRINTER data now analysed, we are exploring all avenues in order to expedite the development of SNG001.

Manufacturing & distribution

Manufacturing pharmaceutical products has been very challenging due to COVID-19, with shortages in key ingredients, components, equipment and manufacturing slots. Despite these challenges, Synairgen made good progress in commercial scale manufacturing processes for drug substance and drug product, and continued to build inventory, distribution, pre-commercialisation and commercialisation capabilities:

- Process Performance Qualification commercial scale manufacturing batches of the drug substance (the raw ingredient IFN-beta) with our partner Akron Biotechnology;

- Drug product in pre-filled glass syringes (the finished format, ready-to-use) in partnership with Catalent at commercial supportive scale following completion of Process Performance Qualification;
- Completed a commercial scale manufacturing batch and testing using polyethylene blow-fill-seal container technology to mitigate against the global supply chain shortages of medical grade glass and the reduction of available syringe filling manufacturing slots caused by the number of vaccines and therapeutics in development for COVID-19;
- Long-term stability studies for both drug substance and drug product initiated to support regulatory submissions; and,
- Built inventory of certain specific long-lead time items needed to administer the drug to patients.

The progress made in manufacturing during the year means the Company is in a good position to support further potential clinical trials in COVID-19 and for other viruses that cause hospitalisations.

In readiness for a possible regulatory authorisation in the US, the Company also made good progress in identifying potential COVID-19-experienced partners for in-market support activity such as pharmacovigilance and medical affairs to support healthcare professionals and patient support programmes. Synairgen also identified the required structure and roles for a US commercial organisation and these can be mobilised in the future as required but due to cost conservation currently there is no requirement to deploy such US personnel.

FINANCIAL REVIEW

Statement of Comprehensive Income

The loss from operations for the year ended 31 December 2021 was £57.9 million (2020: £17.7 million) with research and development expenditure amounting to £52.9 million (2020: £15.5 million) and other administrative expenses of £5.0 million (2020: £2.2 million).

Clinical trial expenditure increased significantly during 2021 as the Phase 3 SPRINTER trial commenced patient recruitment in January 2021. Other clinical trial expenditure included the completion of the SG016 Home trial and the ACTIV-2 trial, including some preparatory costs for the Phase 3 element of the trial. Alongside the clinical trial activity, regulatory activities were increased in preparation for potential regulatory submissions in 2022.

The remainder of the research and development expenditure has been focussed on upscaling SNG001 manufacturing development activities and procuring long lead time components. A number of drug substance commercial scale batches were completed during 2021, including three Process Performance Qualification (PPQ) batches. Two different drug product activities were advanced during the year, with PPQ batches of both pre-filled

glass syringes and polyethylene blow-fill-seal containers being manufactured. The Company has also invested in the development of release assays at a US-based supplier. The internal Chemistry Manufacturing and Controls (CMC) team has been strengthened during the year with a number of new senior hires.

Other administrative expenses increased from £2.2 million to £5.0 million. The increase was attributable firstly to the establishment of a commercial team and preparatory activities for a potential launch in 2022, and secondly, to the increase in administrative and financial personnel and professional costs to accommodate the increase in scale of the business.

The research and development tax credit increased from £3.8 million to £9.2 million on account of the increased qualifying project expenditure, primarily on the SPRINTER trial and manufacturing development activities. The credit equates to 17% of our 2021 research and development expenditure (2020: 25%).

The loss after tax for 2021 was £48.7 million (2020: £13.9 million) and the basic loss per share was 24.28p (2020: basic loss per share of 9.46p).

Statement of Financial Position and Cash Flows

At 31 December 2021, net assets amounted to £37.0 million (2020: £85.1 million), including cash balances of £33.8 million (2020: £75.0 million).

The principal elements of the £41.2 million decrease during the year ended 31 December 2021 (2020: £72.5 million increase) in cash balances were:

- Cash outflows from operations before changes in working capital: £57.2 million (2020: £17.3 million), with the increase being attributable to the higher operating loss as discussed above;
- Changes in working capital: £12.2 million inflow (2020: £7.5 million outflow) on account of the reduction in trade and other receivables and the increase in trade and other payables as detailed below;
- Research and development tax credits received: £3.9 million (2020: £0.9 million) on account of the increased 2020 tax credit;
- Share issue proceeds (net of costs): £nil (2020: £97.9 million); and,
- Net settlement of options £nil (2020: £1.3 million outflow).

The other significant changes in the statement of financial position were:

- Current tax receivable increased from £3.8 million to £9.1 million on account of the higher research and development tax credit receivable;
- Trade and other receivables decreased from £9.4 million to £1.5 million on account of a reduction in manufacturing and clinical trial prepayments; and,
- Trade and other payables increased from £3.3 million to £7.6 million, reflecting the increased level of activity.

OUTLOOK

On the back of the data from the Phase 3 SPRINTER trial and subsequent analyses of different high-risk patient groups within the trial, we are encouraged that SNG001 has the potential to show clinically important benefits in preventing disease progression and death. This data was well received at the recent ATS International Conference in San Francisco in mid-May 2022. We are now, working in haste, fully focussed on discussions with platform trial organisers and investigators, as well as regulatory authorities, the pharmaceutical and biotech industry and government bodies to identify and establish the optimal method of conducting further trials to confirm these findings and provide the Company with the evidence required for a regulatory submission. In addition, building on our existing body of evidence, we are actively exploring the opportunity to collaborate and trial the product as a broad-spectrum, virus-agnostic treatment in patients hospitalised with a range of seasonal viruses such as influenza, RSV and para-influenza.

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Consolidated Statement of Comprehensive Income

for the year ended 31 December 2021

	Notes	**Year ended 31 December 2021 £000**	Year ended 31 December 2020 £000
Research and development expenditure		**(52,857)**	(15,495)
Other administrative expenses		**(5,009)**	(2,246)
Total administrative expenses and Loss from operations		**(57,866)**	(17,741)
Finance income		**11**	19
Finance expense		**(2)**	(10)
Loss before tax		**(57,857)**	(17,732)
Tax	2	**9,194**	3,816
Loss and total comprehensive loss for the period attributable to equity holders of the parent		**(48,663)**	(13,916)
Loss per ordinary share	3		
Basic and diluted loss per share (pence)		**(24.28)p**	(9.46)p

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Consolidated Statement of Changes in Equity

for the year ended 31 December 2021

	Share capital £000	Share premium £000	Merger reserve £000	Retained deficit £000	Total £000
At 1 January 2020	1,094	28,262	483	(27,586)	2,253
Issue of ordinary shares	905	100,170	-	-	101,075
Transaction costs in respect of share issues	-	(3,187)	-	-	(3,187)
Recognition of share-based payments	-	-	-	207	207
Net settlement of share options	-	-	-	(1,291)	(1,291)
Loss and total comprehensive loss for the year	-	-	-	(13,916)	(13,916)
At 31 December 2020	1,999	125,245	483	(42,586)	85,141
Issue of ordinary shares	14	-	-	-	14
Recognition of share-based payments	-	-	-	508	508
Loss and total comprehensive loss for the year	-	-	-	(48,663)	(48,663)
At 31 December 2021	**2,013**	**125,245**	**483**	**(90,741)**	**37,000**

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Consolidated Statement of Financial Position

as at 31 December 2021

	31 December 2021 £000	31 December 2020 £000
Assets		
Non-current assets		
Intangible assets	**53**	44
Property, plant and equipment	**173**	250
Right-of-use assets	**-**	94
	226	388
Current assets		
Inventories	**-**	41
Current tax receivable	**9,055**	3,771
Trade and other receivables	**1,530**	9,372
Cash and cash equivalents	**33,827**	74,976
	44,412	88,160
Total assets	**44,638**	88,548
Liabilities		
Current liabilities		
Trade and other payables	**(7,638)**	(3,279)
Lease liabilities	**-**	(128)
Total liabilities	**(7,638)**	(3,407)
Total net assets	**37,000**	85,141
Equity		
Capital and reserves attributable to equity holders of the parent		
Share capital	**2,013**	1,999
Share premium	**125,245**	125,245
Merger reserve	**483**	483
Retained deficit	**(90,741)**	(42,586)
Total equity	**37,000**	85,141

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Consolidated Statement of Cash Flows

for the year ended 31 December 2021

	Year ended 31 December 2021 £000	Year ended 31 December 2020 £000
Cash flows from operating activities		
Loss before tax	**(57,857)**	(17,732)
Adjustments for:		
Finance income	**(11)**	(19)
Finance expense	**2**	10
Lease adjustment	**(4)**	-
Depreciation of property, plant and equipment	**92**	90
Depreciation of right-of-use assets	**94**	161
Amortisation of intangible fixed assets	**9**	9
Share-based payment charge	**508**	207
Cash flows from operations before changes in working capital	**(57,167)**	(17,274)
Decrease in inventories	**41**	-
Decrease/(Increase) in trade and other receivables	**7,841**	(9,244)
Increase in trade and other payables	**4,359**	1,789
Cash used in operations	**(44,926)**	(24,729)
Tax credit received	**3,910**	910
Net cash used in operating activities	**(41,016)**	(23,819)
Cash flows from investing activities		
Interest received	**12**	31
Purchase of intangible assets	**(18)**	(37)
Purchase of property, plant and equipment	**(15)**	(39)
Net cash used in investing activities	**(21)**	(45)
Cash flows from financing activities		
Proceeds from issue of ordinary shares	**14**	101,075
Transaction costs in respect of share issues	**-**	(3,187)
Net settlement of share options	**-**	(1,291)
Principal paid on lease liabilities	**(124)**	(196)
Interest paid on lease liabilities	**(2)**	(15)
Net cash (used in)/generated from financing activities	**(112)**	96,386
(Decrease)/Increase in cash and cash equivalents	**(41,149)**	72,522
Cash and cash equivalents at beginning of the year	**74,976**	2,454
Cash and cash equivalents at end of the year	**33,827**	74,976

Notes

1. Basis of preparation

The financial information of the Group set out above does not constitute "statutory accounts" for the purposes of Section 435 of the Companies Act 2006. The financial information for the year ended 31 December 2021 has been extracted from the Group's audited financial statements which were approved by the Board of directors on 24 May 2022 and will be delivered to the Registrar of Companies for England and Wales in due course. The financial information for the year ended 31 December 2020 has been extracted from the Group's audited financial statements for that period which have been delivered to the Registrar of Companies for England and Wales. The reports of the auditors on both these financial statements were unqualified, did not include any references to any matters to which the auditors drew attention by way of emphasis without qualifying their report and did not contain a statement under Section 498(2) or Section 498(3) of the Companies Act 2006. Whilst the financial information included in this preliminary announcement has been prepared in accordance with the recognition and measurement criteria of UK adopted International Financial Reporting Standards ('IFRSs'), this announcement does not itself contain sufficient information to comply with those IFRSs. This financial information has been prepared in accordance with the accounting policies set out in the December 2021 report and financial statements.

2. Tax

The tax credit of £9,194,000 (2020: £3,816,000) relates to research and development tax credits in respect of the year ended 31 December 2021 (£9,055,000) and an adjustment in respect of prior periods (£139,000).

3. Loss per ordinary share

Basic loss per share is calculated by dividing the loss attributable to ordinary equity holders of the parent company by the weighted average number of ordinary shares in issue during the year.

The loss attributable to ordinary shareholders and weighted average number of ordinary shares for the purpose of calculating the diluted earnings per ordinary share are identical to those used for basic loss per share. This is because the exercise of share options would have the effect of reducing the loss per ordinary share and is therefore antidilutive under the terms of IAS 33.